

Remarks

Claims 1-31 are pending in this application. Claims 32-59 were withdrawn by the Examiner as being directed to an invention that is independent or distinct from the invention originally claimed. Applicants reserve the right to prosecute claims 32 - 59 in a continuing application. Claim 1 has been amended. No new matter has been added, as the amendment is supported by the specification as originally filed.

Request for Withdrawal of Final Rejection

As a preliminary matter, applicants respectfully request that the examiner withdraw the final rejection of claims 1-31 as being premature, since the examiner has introduced new grounds of rejection that were neither necessitated by applicants' previous amendment of the claims nor based on information submitted in an information disclosure statement filed during the period set forth in 37 C.F.R. 1.97(c).

Reconsideration and allowance of the present application in view of the above amendment and the following remarks is respectfully requested.

In the Office Action dated March 31, 2004, the Examiner:

- withdrew claims 31-59 from further consideration pursuant to 37 C.F.R. 1.142(b), as being drawn to an invention that is independent or distinct from the invention originally claimed.
- withdrew rejections of claims 1, 4, 5, 10 and 31 under 35 U.S.C. 112(2);
- withdrew 35 U.S.C. §102(b) rejections of claims 1-5, 7-12, 16, 17, 21-23 and 29-31 over WO 93/20859 to Arm et al ("the Arm PCT application"); withdrew the 35 U.S.C. §102(b) rejections of claims 1, 2, 4, 5, 8-10 and 20 over U.S. Patent No. 4,610,692 to Eitenmuller et al ("the Eitenmuller patent"), and withdrew the 35 U.S.C. §102(b) rejections of claims 1-6, 8-12 and 20 over U.S. Patent No. 5,670,161 to Healy et al. ("the Healy patent").
- rejected claims 1-5, 7-19 and 21-31 under 35 U.S.C. 103(a) as being unpatentable over the Arm PCT application;
- rejected claims 1, 2, 4, 5, 8-10 and 20 under 35 U.S.C. 103(a) as being unpatentable over the Eitenmuller patent;
- rejected claims 1-6, 8-12 and 20 were rejected under 35 U.S.C. 103(a) as being unpatentable over the Healy patent.

Claim Rejections - 35 U.S.C. § 103(a)Independent Claim 1The Arm PCT Application

Independent claim 1 was rejected under 35 U.S.C. § 103(a) as being unpatentable over the Arm PCT application. Claim 1 has been amended to recite "Implant for compensating for pathological changes in the spinal column or locomotor system, the implant comprising a body having a varnish-like biodegradable polymer coating of a thickness of 100 µm or less, wherein the body has a substantially constant physiochemical state under physiological conditions in vivo."

The Arm PCT application does not disclose, teach or suggest an implant having a "varnish-like" coating as recited by claim 1. In contrast to the varnish-like coating recited by claim 1, Arm discloses wrapping a pre-prepared biodegradable film around surgical screws, rods, pins, plates and the like. (*See* Arm PCT application, 13:6-113).

As previously noted in Applicants Amendment, dated September 29, 2003, the term varnish-like requires that the coating bonds with the surface of the base material with enough adhesive strength such that, when the implant is implanted, mechanical friction will not abrade or otherwise damage the coating, or at least, not to such an extent as to compromise its physical effect. (*See* Specification, 4:28-31). It is this adhesive strength that ensures the coating is not degraded during insertion in the body.

For example, as described in the specification, it is understood that one may properly drive a nail, provided with the varnish-like coating, into the bone without any significant abrasion of the varnish-like coating. (*See* Specification, 4:32-33). The specification notes, for example, that a nail wrapped with a foil cannot be inserted in the medulla in a way that the foil which only loosely envelops the nail, actually reaches the point of its intended healing action. (*See id.*, 1:29-32).

Thus, the Arm PCT application does not disclose, teach or suggest a "varnish-like" coating, but rather discloses wrapping a pre-prepared biodegradable film on surgical screws, rods, pins, plates and the like. (*See* Arm PCT application, 13:6-13). Although the Arm PCT application refers to its wrapped films as "being useful as coatings for prosthetic devices and surgical implants," such is not understood to disclose, teach or suggest the "varnish-like" coating of claim 1, as described above.

Thus, applicants respectfully submit that the Arm PCT application does not disclose, teach or suggest each and every limitation of claim 1. Accordingly, independent claim 1 is

patentable over the Arm PCT application, and thus the rejection of claim 1 under 35 U.S.C. §103(a) should be withdrawn. With respect to claims 2-5, 7-19 and 21-31, which depend from independent claim 1, applicants submit that because these claims define more particular aspects of the applicants' invention in addition to the features and elements of independent claim 1, these claims are also distinguished over the Arm PCT application for at least the same reasons as identified for claim 1.

The Eitenmuller Patent

Independent claim 1 was rejected under 35 U.S.C. § 103(a) as being unpatentable over the Eitenmuller patent. As previously noted, claim 1 has been amended to recite "Implant for compensating for pathological changes in the spinal column or locomotor system, the implant comprising a body having a varnish-like biodegradable polymer coating of a thickness of 100 µm or less, wherein the body has a substantially constant physiochemical state under physiological conditions in vivo."

The Eitenmuller patent does not disclose, teach or suggest "an implant comprising a body having a varnish-like biodegradable polymer coating of a thickness of 100 µm or less, wherein at least a portion of the body has a substantially constant physiochemical state under physiological conditions in vivo" as recited by claim 1. The coated implant of Eitenmuller does not have a substantially constant physiochemical state under physiological conditions in vivo. Rather, the implant of Eitenmuller is designed to release at least one therapeutically-active ingredient which is distributed among the pores within the implant. (See Eitenmuller patent, 5:68-6:1).

Thus, applicants respectfully submit that the Eitenmuller patent does not disclose, teach or suggest each and every limitation of claim 1. Accordingly, independent claim 1 is patentable over the Eitenmuller patent, and the rejection of claim 1 under 35 U.S.C. §103(a) should be withdrawn. With respect to claims 2, 4, 5, 8-10 and 20, which depend from independent claim 1, applicants submit that because these claims define more particular aspects of the applicants' invention in addition to the features and elements of independent claim 1, these claims are also distinguished over the Eitenmuller patent for at least the same reasons as identified for claim 1.

The Healy Patent

Independent claim 1 was rejected under 35 U.S.C. § 103(a) as being unpatentable over the Healy patent. As previously described, claim 1 has been amended to recite "Implant for compensating for pathological changes in the spinal column or locomotor system, the implant comprising a body having a varnish-like biodegradable polymer coating of a

thickness of 100 µm or less, wherein the body has a substantially constant physiochemical state under physiological conditions in vivo."

The Healy patent does not disclose, teach or suggest "an implant comprising a body having a varnish-like biodegradable polymer coating of a thickness of 100 µm or less, wherein the body has a substantially constant physiochemical state under physiological conditions in vivo" as recited by claim 1. Rather, Healy discloses a biodegradable stent. The biodegradable stent of Healy, therefore, does not have a substantially constant physiochemical state under physiological conditions in vivo as required by claim 1. Hence, applicants respectfully submit that Healy does not disclose, teach or suggest each and every limitation of claim 1. Accordingly, independent claim 1 is patentable over the Healy patent, and thus the rejection of independent claim 1 under 35 U.S.C. §103(a) should be withdrawn. With respect to claims 2-6, 8-12 and 20, which depend from independent claim 1, applicants submit that because these claims define more particular aspects of the applicants' invention in addition to the features and elements of independent claim 1, these claims are also distinguished over the Healy patent for at least the same reasons as identified for claim 1.

In view of the foregoing amendments and remarks, it is submitted that all rejections have been overcome and should be withdrawn, and all claims are in condition for allowance. Reconsideration of the application in view of the foregoing amendments and remarks is respectfully requested. The Examiner is invited to call the undersigned if a telephone call could help resolve any remaining items.

Respectfully submitted,



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